UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456 Master File No. 1:01-CV-12257-PBS Sub-Category Case No. 1:08-CV-11200
THIS DOCUMENT RELATES TO: *United States ex rel. Linnette Sun and Greg Hamilton, Relators* *v.* *Baxter Healthcare Corporation*	Judge Patti B. Saris

MEMORANDUM IN SUPPORT OF BAXTER HEALTHCARE CORPORATION'S PARTIAL MOTION TO DISMISS

Pursuant to 31 U.S.C. § 3730(b)(5) – the so-called "first-to-file" bar – the Court lacks jurisdiction over Count One of the Sun/Hamilton Complaint as it relates to Baxter's hemophilia therapy Recombinate and, therefore, over the only remaining claim by Relator Hamilton. Only Sun's False Claims Act ("FCA") allegations regarding Advate should be the subject of any further litigation.[1]

During oral argument on February 9, 2010, the Court granted Baxter's motion to dismiss Counts I (for all drugs other than Advate and Recombinate), II, III, and VII-XXI of the Complaint. The Court's March 25 Order repeated the February 9 rulings,[2] including the denial in part of Baxter's motion to dismiss the Count 1 FCA claims regarding Advate and Recombinate. The Court ruled, *inter alia*, that Sun – a former Baxter employee "involved with the pricing of Baxter's drugs, specifically Advate" – qualified as an original source. March 25

[1] The only other surviving counts (Counts IV, V, VI, XXII, and XXIII) relate to Sun's retaliation and employment discrimination claims. *United States ex rel. Sun v. Baxter Hemoglobin Therapeutics, et al. (In re Pharm. Indus. Average Wholesale Price Litig.)*, No. 08-11200-PBS, 2010 WL 1375298, at *1 n.1 (D. Mass. Mar. 25, 2010) ("March 25 Order").

[2] *See* March 25 Order, at *1 n.1.

Order, at *4. Hamilton's status as an original source – which the Court described as "a closer question" – was based upon a conversation Hamilton had with a First Data Bank employee regarding the Baxter therapy Recombinate. *Id.* at *4.

Several months after the February 9 hearing and March 25 Order, Ven-A-Care's Complaint against Baxter was unsealed. The Ven-A-Care Complaint, which was first filed in 1995, makes the same AWP allegations regarding Recombinate as are made in the Sun/Hamilton Complaint. The Recombinate-related claim in the Sun/Hamilton Complaint thus must be dismissed under the first-to-file bar.

I. FACTS

A. Sun/Hamilton Complaints

Sun and Hamilton filed their original complaint on April 22, 2005 in the District of Colorado. Exhibit ("Ex.") 1 ("Sun/Hamilton Complaint"). The first Amended Complaint, filed on June 14, 2005, added Sun's discrimination and harassment claims under California law (Counts XXII and XXIII).[3] Both complaints named Baxter Hemoglobin Therapeutics and Baxter International Inc. as defendants. The Department of Justice ("DOJ") declined to intervene and the Amended Complaint was unsealed on January 15, 2008. Baxter International, Inc. was served on May 12, 2008, and the case was consolidated with MDL 1456 on July 15, 2008.

A Second Amended Sun/Hamilton Complaint was filed on August 13, 2010.[4] That complaint added Baxter Healthcare Corporation as a defendant; Relators dismissed the other two

[3] Amended Sun/Hamilton Complaint ¶¶ 253-265 (filed June 14, 2005) (Sun Docket No. 57, Attachment #2).

[4] Second Amended Sun/Hamilton Complaint (filed August 13, 2010) (Sun Docket No. 102).

Baxter entities on August 30, 2010. All three versions of the Sun/Hamilton Complaint contain the same allegations about Recombinate.

B. Ven-A-Care Complaints

In May 2010, Baxter Healthcare Corporation and Baxter International Inc. were served with an unsealed complaint filed by *qui tam* Relator Ven-A-Care of the Florida Keys, Inc. Ven-A-Care filed its original complaint under seal on June 23, 1995, and filed multiple amended complaints between 1995 and 2010.

At the time the Sun/Hamilton Complaint was filed, the Ven-A-Care Complaint then in effect was the "Fourth Amended Complaint for Money Damages and Civil Penalties Under the False Claims Act." The Fourth Amended Ven-A-Care Complaint was filed on December 22, 2002. Ex. 2 ("Ven-A-Care Complaint").

The Sun/Hamilton and Ven-A-Care Complaints contain very similar FCA claims regarding Recombinate.

II. ARGUMENT

A. Recombinate Should Be Dismissed from Count One

The FCA provides that "[w]hen a person brings an action under this subsection, no person other than the Government may intervene or bring a related action based on the facts underlying the pending action." 31 U.S.C. §3730(b)(5). The first-to-file bar "prevents private plaintiffs 'from bringing related actions based on the same underlying facts.'" *See United States ex rel. Ven-A-Care of the Fla. Keys, Inc. v. Abbott Labs., Inc. (In re Pharm. Indus. Average Wholesale Price Litig.)*, No. 07-11618-PBS, 2008 WL 2778808, at *2 (D. Mass. July 15, 2008) ("Abbott Labs.") (quoting *United States ex rel. Lujan v. Hughes Aircraft Co.*, 243 F.3d 1181, 1187 (9th Cir. 2001)). The rule "furthers the policy of the FCA in that '[t]he first-filed claim

provides the government notice of the essential facts of an alleged fraud, while the first-to-file bar stops repetitive claims.'" *Abbott Labs.*, 2008 WL 2778808, at *2 (citation omitted).

The first-to-file bar is "'not limited to situations in which the original and subsequent complaints rely on identical facts.'" *Id*. (quoting *Grynberg v. Koch Gateway Pipeline Co.*, 390 F.3d 1276, 1279 (10th Cir. 2004)). As the First Circuit noted, "[a]ll courts that have addressed the issue have interpreted § 3730(b)(5) to bar a later allegation if it states all the *essential facts* of a previously-filed claim or the same *elements* of a fraud described in an earlier suit. Under this 'essential facts' standard, § 3730(b)(5) can still bar a later claim even if that claim incorporates somewhat different details." *United States ex rel. Duxbury v. Ortho Biotech Prods.*, 579 F.3d 13, 32 (1st Cir. 2009) (citations and internal punctuation omitted). Because "details" may vary, two complaints should be compared "at a sufficiently high level of generality." *United States ex rel. Folliard v. CDW Tech. Serv. Inc.*, 722 F. Supp. 2d 37, 41 (D.D.C. 2010).

B. The Sun/Hamilton Complaints State the Same "Essential Facts" As the Previously-Filed Ven-A-Care Complaints

The Ven-A-Care and Sun/Hamilton complaints allege that Baxter violated the FCA by knowingly submitting inflated pricing information to drug pricing compendia, thereby causing Medicare, Medicaid, and other payors to pay falsely inflated reimbursement amounts. *See generally* Ven-A-Care Complaint (Ex. 2) ¶¶ 1-5, 177-78; Sun/Hamilton Complaint (Ex. 1) ¶¶ 2, 5, 32-35. Both complaints contain the "essential facts" that Baxter marketed the spread to increase profitability (*e.g.*, Ven-A-Care Complaint (Ex. 2) ¶¶ 3, 9, 14, 177; Sun/Hamilton Complaint (Ex. 1) ¶¶ 5, 6, 32, 34, 36); that it knowingly reported falsely inflated average wholesale prices ("AWPs") and wholesale acquisition costs ("WACs") to pricing publications (*e.g.*, Ven-A-Care Complaint (Ex. 2) ¶¶ 74, 178; Sun/Hamilton Complaint (Ex. 1) ¶¶ 2, 4, 6, 31, 32, 36, 38, 39); that it did so to pricing publications, specifically including First DataBank (*e.g.*,

Ven-A-Care Complaint (Ex. 2) ¶¶ 67, 178; Sun/Hamilton Complaint (Ex. 1) ¶¶ 1, 31, 35, 38); and that it knew Medicare, Medicaid, and other payors would use the falsely inflated published pricing information provided by Baxter to determine reimbursement (*e.g.*, Ven-A-Care Complaint (Ex. 2) ¶¶ 3, 4, 12, 177; Sun/Hamilton Complaint (Ex. 1) ¶¶ 25, 26, 32, 36).

The following complaint excerpts are provided by way of example:

- On marketing the spread:

  > [Baxter] knowingly opted to report inflated prices and costs for the express purpose of creating a "Spread" between the resulting Medicare/Medicaid reimbursement amounts and the prices actually being charged to the Providers. The Spread served as an inducement to Providers to purchase the specified drugs. Ven-A-Care Complaint (Ex. 2) ¶ 3.
  >
  > The effect of Baxter's false reporting [of prices] was that Baxter illegally increased the profitability, or spread, of these drugs to health care providers and pharmacies, thus giving a financial incentive for their selection and use. Sun/Hamilton Complaint (Ex. 1) ¶ 32.

- On reporting an inflated WAC:

  > [Baxter's] use of the "charge-back" device . . . permitted [Baxter] to control prices charged by wholesalers while falsely reporting an inflated wholesaler cost by excluding the often significant impact of the charge-back on the net effective wholesale acquisition cost. Ven-A-Care Complaint (Ex. 2) ¶ 74.
  >
  > Although the charge-back wholesalers purchased less than 1% of the biologicals, Baxter reported to FDB that the high prices charged to this tiny market segment was its WAC. . . . Since the price charged to less than 1% of its market did not affect sales, Baxter could use it to manipulate the reimbursement system since the published AWP had no correlation to the price charged to the wholesalers that distributed nearly all of Baxter's biologicals. Sun/Hamilton Complaint (Ex. 1) ¶ 31.

- On payors relying on the published pricing information to determine reimbursement:

  > [Baxter was] fully aware of the Medicare and Medicaid reimbursement methodologies and of the fact that

> Medicare/Medicaid was required to use drug manufacturers', including [Baxter's] reported drug prices and costs in establishing Provider reimbursement amounts. . . . [Baxter] knew that the Medicare and State Medicaid Programs intended to base their payments of "reimbursement" for the specified drugs on reasonable estimations of the drug's cost and that Medicare/Medicaid utilized the falsely inflated prices and costs reported by [Baxter] in estimating reimbursement. Ven-A-Care Complaint (Ex. 2) ¶¶ 3, 12.

> Medicaid, Medicare, and all other systems which base reimbursement rates for drugs on the published AWP . . . depend upon the honesty and accuracy of Baxter and other drug manufacturers in reporting WAC to FDB. . . . Providers regularly submit claims for reimbursement seeking payment for Baxter's products from Medicare, Medicaid, and from other federal payors. Manufacturers, including Baxter, were and are fully aware that these payors also rely on FDB's published reports of AWP to determine their reimbursement. Sun/Hamilton Complaint (Ex. 1) ¶¶ 25, 26.

Both Ven-A-Care and Sun/Hamilton name Recombinate as one of the Baxter therapies involved in the alleged FCA scheme. *See* Ex. 3 (Ven-A-Care Complaint, Exhibit 6) at pp. 97-98; Sun/Hamilton Complaint (Ex. 1) ¶¶ 20, 36. This Court previously held that the same specific drug must be named in both complaints to trigger the first-to-file bar because "drugs are often marketed, reimbursed, sold, and priced in different ways." *Abbott Labs.*, 2008 WL 2778808, at *3. Because Ven-A-Care identified Recombinate as one of the Baxter therapies covered by its false claims allegations in 2002,[5] over two years before the Sun/Hamilton Complaint, Sun/Hamilton cannot assert claims about the same therapy. The Ven-A-Care and Sun/Hamilton complaints clearly contain the same "essential facts," as well as many supporting details, relating to the false claims allegations concerning Recombinate. The Ven-A-Care Complaint "provide[d] the government with notice of the essential fact that the alleged

[5] Ven-A-Care's 1997 amended complaint also identified Recombinate as a subject drug. *See* 1:10-cv-11186-PBS at 43 (Ven-A-Care Docket No. 5-1).

fraudulent scheme involved" Recombinate. The Recombinate-related FCA allegation in the Sun/Hamilton Complaint is therefore barred.

C. Hamilton Should Be Dismissed as a Relator Because His "Original Source" Knowledge Is Limited to Recombinate

Based upon the Court's prior rulings, the only remaining Count that involves Hamilton is Count I, and Hamilton's original source status for that Count relates only to Recombinate. This Court held that Hamilton had knowledge of an "essential element of the underlying fraud transaction, that Baxter was reporting only misleading list sales prices to FDB, specifically for Recombinate." March 25 Order, at *4 (citation and internal punctuation omitted). No information in the Sun/Hamilton Complaint, other than the allegations concerning Recombinate, can be attributed to Hamilton.[6] If Recombinate is removed from the case, only Advate remains. But the Court has ruled that the original source for the Advate information in the Complaint was Sun. *Id*. at *4 ("Sun was intimately involved with the pricing of Baxter's drugs, specifically Advate."). Hamilton should be dismissed from this case because his Recombinate knowledge and allegations are essentially the same as those in the Ven-A-Care Complaint. Hamilton is not an original source for the remaining Advate claim.

This Court has ruled that, "[o]nce the government is put on notice of its potential fraud claim, the purpose behind allowing qui tam litigation is satisfied." *Abbott Labs.*, 2008 WL

[6] Although he has implied numerous times that he provided other facts about Baxter, at no point has Hamilton been able to substantiate these claims. *See* Memorandum in Support of Baxter International Inc.'s Motion to Dismiss Relators' Complaint, filed August 14, 2009 (Sun Docket No. 66) at 11-13; Baxter International Inc.'s Reply in Further Support of Its Motion to Dismiss Relators' Complaint, filed September 30, 2009 (Sun Docket No. 76) at 6-8; Baxter International Inc.'s Supplemental Reply Brief in Further Support of its Motion to Dismiss Relators' Complaint, filed January 27, 2010 (Sun Docket No. 84) at 4-8. Hamilton's deposition makes clear that he has no additional information to add. *See* Exhibit A to the July 29, 2011 Declaration of Shamir Patel in Support of Baxter Healthcare's Partial Motion to Dismiss (Hamilton January 21, 2010 Deposition Transcript) at 30:3-6; 78:18-85:9; 89:9-98:9.

2778808, at *2 (citation and internal punctuation omitted). Hamilton provided only information concerning Recombinate; Ven-A-Care filed its Recombinate claim first; Hamilton therefore has no basis to remain as a qui tam relator.

In *Folliard*, 722 F. Supp. 2d at 43, a relator and his complaint were dismissed under the first-to-file bar because the later-filing relator "never worked for the defendants, and his complaint contain[ed] no 'insider' information that a DOJ attorney who was already investigating [the first-filed] complaint could not have learned." Here, a DOJ attorney investigating the Ven-A-Care Complaint would have learned that Recombinate was one of the drugs named by Ven-A-Care as part of its FCA allegations against Baxter in 2002.[7] The Government would have learned nothing more from Hamilton over two years later. Allowing Hamilton to remain in this case would contravene the policy underlying 31 U.S.C. § 3730, which, as this Court has noted, is a balancing act between "'adequate incentives for whistle-blowing insiders with genuinely valuable information and discouragement of opportunistic plaintiffs who have no significant information to contribute of their own.'" *United States ex rel. West, et al., v. Ortho-McNeil Pharm., Inc. and Johnson & Johnson (In re Pharm. Indus. Average Wholesale Price Litig.)*, 538 F. Supp. 2d 367, 376 (D. Mass. 2008) (citation omitted).

Hamilton cannot continue as an original source because he has no "direct and independent" knowledge to support the remaining Advate-related FCA claim. *See* 31 U.S.C. § 3730(e)(4)(B).[8] In *Duxbury*, 579 F.3d at 28, the First Circuit upheld the dismissal of one of two relators, and the claims attributable to him, after he failed to establish his original source

[7] Indeed, DOJ would have learned this even as early as 1997. *See supra* at 6, n.5.

[8] The definition of "original source" in 31 U.S.C. § 3730(e)(4)(B) was revised effective March 23, 2010. However, this revision should not be applied retroactively to suits instituted prior to that date. *See Graham County Soil & Water Conservation Dist. v. U.S. ex rel. Wilson*, 130 S. Ct. 1396, 1400 n.1 (2010); *Hughes Aircraft Co. v. U.S. ex rel. Schumer*, 520 U.S. 939, 948 (1997).

status. *See also United States ex rel. Hutcheson v. Blackstone Med., Inc.*, 694 F. Supp. 2d 48, 60 (D. Mass. 2010) (dismissing the relator who made a "comparatively weaker" contribution to the complaint and who could not demonstrate that he was an original source), *rev'd on other grounds*, No. 10-1505, 2011 U.S. App. LEXIS 10972 (1st Cir. June 1, 2011).

The Court found Hamilton to be an original source with respect to Recombinate. As the Recombinate-related FCA claim must be dismissed under the first-to-file bar, and as Hamilton has not established that he can be an original source with respect to the Advate-related claim, Hamilton should be dismissed as a Relator in this case.

D. The Sun/Hamilton Complaint Alleges No Facts That Evidence a Distinct Scheme

Relators have previously taken the position that the Sun/Hamilton Complaint involves a "new species of AWP fraud" not contained in the Ven-A-Care Complaint. Relators' Opposition to Baxter's Motion to Dismiss (Sun Docket No. 72) at 2-6. The Court rejected this "new species" argument when the Court dismissed all other FCA allegations of the Sun/Hamilton Complaint and it should do the same if asked to reconsider such a defense now. Relators cannot successfully rely upon *Duxbury* to escape the jurisdictional bar over their Recombinate claims.

The Sun/Hamilton Complaint alleges no facts that evidence a scheme that is distinct from or more widespread than the scheme alleged by Ven-A-Care. All manner of alleged AWP fraud – whether based upon a markup from WAC, list price, or on straight AWP price reporting – is redundant of the Ven-A-Care Complaint, which alleges that reimbursement was too high because of an inflated AWP caused by Baxter's alleged reporting practices. In *United States ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, 551 F. Supp. 2d 100 (D. Mass. 2008), the district court compared the allegations of two complaints filed under the False Claims Act to determine

which was "first" to sufficiently state claims for an off-label marketing scheme of a drug (Procrit) used to treat anemia.[9] The court found that the original complaint had made only a "bare bones allegation" that could "not act as a placeholder for the widespread off-label marketing scheme that Relators now wish to allege." *Id.* at 114. The second-filed complaint detailed a widespread scheme that involved a variety of marketing and incentive programs (including direct off-label marketing, improper influence of clinical studies, illegal payments, rebate programs, and the use of conferences to push the product), while the original complaint did not provide any of the essential facts regarding this scheme, and, in fact, alleged only that "one [clinical] trial in 1997, and not any other . . . [manufacturer] activities or initiatives, led physicians to switch to the higher dosage of Procrit." *Id.* The First Circuit affirmed this part of the district court's decision, noting that original complaint "nowhere referred to an 'off-label' promotion scheme" at all. *Duxbury*, 579 F.3d at 33.[10]

[9] In looking at the first-to-file issue other courts have considered both the similarity of factual allegations and the extent to which recovery would be duplicative. In *Erickson ex rel. United States v. American Inst. of Biological Sciences*, 716 F. Supp. 908, 918 (E.D. Va. 1989), the court held that a "subsequently filed *qui tam* suit may continue only to the extent that it is (a) based on facts different from those alleged in the prior suit and (b) gives rise to separate and distinct recovery by the government." This two-pronged approach has been followed by the District of Connecticut, in *United States ex rel. Capella v. United Techs. Corp.*, No. 3:94-cv-2063, 1999 U.S. Dist. LEXIS 10520, at *26-27 (D. Conn. 1999) and *United States ex. rel. Smith v. Yale-New Haven Hosp, Inc.*, 411 F. Supp. 2d 64, 76 (D. Conn. 2005), and by the District of Columbia, in *United States ex rel. Ortega v. Columbia Healthcare*, 240 F. Supp. 2d 8, 12 (D.D.C. 2003). In *Smith*, the court explained the benefit of using the hybrid approach for a first-to-file analysis: "the hybrid approach is helpful looking to whether the complaints allege the same material facts, i.e. whether they involve the same core conduct, and would give rise to separate recovery. *Smith*, 411 F. Supp. 2d at 76. Here, the Ven-A-Care and Sun/Hamilton complaints allege facts that give rise to identical recovery concerning Recombinate.

[10] Similarly, using the reasoning of *Duxbury*, this Court ruled that the first-to-file rule did not bar a claim where the second complaint not only was the first to plead the essential facts of a widespread "overfill" marketing scheme for a particular drug, but also was the first to allege a particular methodology of inducing providers to purchase the drug. *United States v. Amgen, Inc.*, 707 F. Supp. 2d 123, 130 (D. Mass. 2010). In contrast, the Sun/Hamilton Complaint has not alleged a new scheme, nor has is it alleged a new methodology to implement an alleged scheme.

Here, the Sun/Hamilton Complaint has not alleged a distinct or more widespread scheme and no effort by relators to cast their claim as a "new species" can change that fact.

III. CONCLUSION

Pursuant to 31 U.S.C. §3730(b)(5), the Court lacks jurisdiction over the Count 1 FCA allegations regarding Recombinate. At best, Sun remains a viable relator regarding Advate, which will be the sole Baxter therapy remaining in this litigation. Hamilton should similarly be dismissed from the case entirely as he is no longer a viable relator.

Respectfully submitted,

Dated: July 29, 2011

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CERTIFICATE OF SERVICE

I hereby certify that I, Shamir Patel, an attorney, electronically filed the foregoing Memorandum in Support of Baxter Healthcare Corporation's Partial Motion to Dismiss with the Clerk of the Court for the District of Massachusetts using the Court's CM/ECF system on July 29, 2011. I also caused a true and correct copy of the foregoing document to be delivered to all counsel of record by electronic service via LexisNexis File & Serve, for posting and notification to all parties.

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